

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Hospital and Provider Operations

4 (Amendment)

5 907 KAR 1:350. Coverage and payments for organ transplants.

6 RELATES TO: KRS 205.520, 42 CFR 447.53

7 STATUTORY AUTHORITY: KRS 194.050[, ~~EO 2004-726~~]

8 NECESSITY, FUNCTION, AND CONFORMITY: [~~EO 2004-726, effective July 9, 2004,~~
9 ~~reorganized the Cabinet for Health Services and placed the Department for Medicaid Ser-~~
10 ~~vices and the Medicaid Program under the Cabinet for Health and Family Services.~~] The
11 Cabinet for Health and Family Services has responsibility to administer the Medicaid Pro-
12 gram [~~of Medical Assistance in accordance with Title XIX of the Social Security Act~~]. KRS
13 205.520 empowers the cabinet, by administrative regulation, to comply with any require-
14 ment that may be imposed, or opportunity presented, by federal law for the provision of
15 medical assistance to Kentucky's indigent citizenry. This administrative regulation estab-
16 lishes provisions related to the coverage of [~~sets forth the coverage and payments policy~~
17 ~~of the cabinet with regard to~~] organ transplants.

18 Section 1. Definitions.

19 (1) "Department" means the Department for Medicaid Services or its designee.

20 (2) "Emergency" means that a condition or situation requires an emergency service
21 pursuant to 42 CFR 447.53.

1 (3) "Experimental" means that a procedure has not previously been proven effective
2 in treating a patient's health condition.

3 (4) "Medical necessity" or "medically necessary" means that a covered benefit is de-
4 termined to be needed in accordance with 907 KAR 3:130.

5 (5) "Non-emergency" means that a condition does not require an emergency service
6 pursuant to 42 CFR 447.53.

7 Section 2. Prior Authorization.

8 (1) Prior to coverage of an organ transplant, the transplant shall be determined by the
9 department to be:

10 (a) Medically necessary; and

11 (b) Clinically appropriate pursuant to the criteria established in 907 KAR 3:130.

12 (2) The requirements established in subsection (1) of this section shall not apply to an
13 emergency service.

14 Section 3. General Coverage Criteria. A covered organ transplant shall meet the fol-
15 lowing criteria:

16 (1) Effective August 1, 2006, the transplant shall be clinically appropriate pursuant to
17 the criteria established in 907 KAR 3:130;

18 (2) A transplant surgeon's opinion shall conclude that:

19 (a) The transplant is medically necessary in accordance with 907 KAR 3:130; and

20 (b) Failure to perform the transplant would create a life-threatening situation;

21 (3) The patient's prognosis shall indicate that there is a reasonable expectation the
22 transplant will be successful and result in prolonged life of quality and dignity;

23 (4) The hospital where the transplant will take place shall:

1 (a) Have a staffed and functioning unit designed for and accustomed to performing the
2 planned organ transplant; and

3 (b) Be recognized as competent by the medical community; and

4 (5) The physician performing the transplant shall be recognized as competent by the
5 medical community.

6 Section 4. Reimbursement for Organ Transplants.

7 (1) Payment to a hospital for an organ transplant shall be set at eighty (80) percent of
8 the hospital's usual and customary charge with total payments not to exceed \$75,000 per
9 transplant.

10 (2) If the payment methodology described in subsection (1) of this section restricts or
11 prohibits the availability of a needed transplant procedure or service, the department's
12 commissioner may approve on a case-by-case basis payment that exceeds \$75,000 per
13 transplant.

14 (3) Reimbursement to a physician for an organ transplant shall be made in accordance
15 with the physician fee schedule.

16 Section 5. Non-covered Services. The department shall not approve a request for an
17 organ transplant if the requested transplant:

18 (1) Fails to meet the criteria of subsections (2) and (3) of this administrative regulation;
19 or

20 (2) Is experimental in nature. [General Coverage Criteria. The following general cov-
21 erage criteria shall be applicable with regard to organ transplants:

22 ~~(1) For an organ transplant to be covered under the Medicaid Program, it must be the~~
23 ~~opinion of the transplant surgeon that the transplant is medically necessary; the failure to~~

1 ~~perform the organ transplant would create a life-threatening situation; and the prognosis~~
2 ~~must be that there is a reasonable expectation the transplant will be successful and result~~
3 ~~in prolonged life of quality and dignity.~~

4 ~~(2) The hospital and physician performing the transplant must be recognized by the~~
5 ~~Medicaid Program as being competent to perform the transplant. A staffed and functioning~~
6 ~~unit at the hospital designed for and/or accustomed to performing transplants of the na-~~
7 ~~ture envisioned, recognized as competent by the medical community, will ordinarily be~~
8 ~~considered competent by the program.~~

9 ~~Section 2. Reimbursement for Organ Transplants. Hospital payments for organ trans-~~
10 ~~plants will be set at eighty (80) percent of actual usual and customary charges with total~~
11 ~~payments not to exceed \$75,000 per transplant without regard to usual program limits on~~
12 ~~hospital length-of-stay. An exception to the maximum payment limit may be made by the~~
13 ~~Commissioner, Department for Medicaid Services, on a case-by-case basis when the~~
14 ~~maximum payment limit restricts or prohibits the availability of the needed transplant pro-~~
15 ~~cedure or service. Physician payments for organ transplants will be at the usual Medicaid~~
16 ~~Program rates.~~

17 ~~Section 3. Application of Organ Transplants Policy. It is the intent of the Department for~~
18 ~~Medicaid Services that the organ transplant policy be applied uniformly and consistently~~
19 ~~so that similarly situated individuals will be treated alike. To accomplish this goal the de-~~
20 ~~partment will use the methodology specified in this section in receiving and processing~~
21 ~~requests for coverage and payments for organ transplants.~~

22 ~~(1) All requests for authorization for organ transplants must be sent to the Commis-~~
23 ~~sioner, Department for Medicaid Services.~~

1 ~~(2) The commissioner will assign the request to appropriate staff for investigation, re-~~
2 ~~port and recommendation. The report shall show whether the person requesting the~~
3 ~~transplant is Medicaid eligible (or approximately when the person will become eligible); the~~
4 ~~type of transplant requested; the name of the facility (and physician if considered neces-~~
5 ~~sary) where the transplant is to be performed; any fee arrangement that has been made~~
6 ~~with the facility and physician (or a statement as to whether there is a disagreement with~~
7 ~~regard to fees); the proposed date of the transplant; the prognosis; a finding as to whether~~
8 ~~the facility/physician is considered qualified for the transplant being considered; and a~~
9 ~~finding as to whether program criteria for coverage is met.~~

10 ~~(3) After consideration of the report and recommendation the commissioner will deter-~~
11 ~~mine whether the general coverage criteria are met and payments for the transplant may~~
12 ~~be made. If the decision is to provide coverage, Medicaid program staff will assist the re-~~
13 ~~cipient with necessary arrangements for the transplant. If the decision is negative, the re-~~
14 ~~cipient will be notified of the manner in which the request does not meet agency guide-~~
15 ~~lines.~~

16 ~~Section 4. Scope of Coverage. This organ transplant policy is applicable with regard to~~
17 ~~the following types of transplant: heart, lung, bone marrow and liver. Other types of trans-~~
18 ~~plants will also be covered under this policy upon identification and request except when~~
19 ~~special treatment of the transplant services is not considered necessary (i.e., usual pro-~~
20 ~~gram coverage and reimbursement is considered adequate), or when the transplant is~~
21 ~~considered by the Department for Medicaid Services to be experimental in nature. The~~
22 ~~Medicaid Program will not cover experimental transplants, i.e., those which have not pre-~~
23 ~~viously been proven effective in resolving the health problems for which the transplant is~~

1 the proposed preferable treatment mode.]

907 KAR 1:350

REVIEWED:

Date

J. Thomas Badgett, MD, PhD, Acting Commissioner
Department for Medicaid Services

Date

Mike Burnside, Undersecretary
Administrative and Fiscal Affairs

APPROVED:

Date

Mark D. Birdwhistell, Secretary
Cabinet for Health and Family Services

A public hearing on this administrative regulation shall, if requested, be held on August 21, 2006 at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by August 14, 2006, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2006. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:350
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Stuart Owen (502-564-6204)

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes provisions related to the coverage of organ transplants.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish provisions related to the coverage of organ transplants.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation fulfills requirements implemented in the authorizing statutes by establishing provisions related to the coverage of organ transplants.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing provisions related to the coverage of organ transplants.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: This amendment establishes the use of criteria by the department to determine the clinical appropriateness of organ transplant requests.
 - (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to establish the use of criteria by the department to determine the clinical appropriateness of organ transplant requests.
 - (c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of the authorizing statutes by establishing the use of criteria by the department to determine the clinical appropriateness of organ transplant requests.
 - (d) How the amendment will assist in the effective administration of the statutes: This amendment will assist in the effective administration of the statutes by establishing the use of criteria by the department to determine the clinical appropriateness of organ transplant requests.
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This amendment will affect all hospitals that are reimbursed by Medicaid for organ transplants.
- (4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: To receive reimbursement, this amendment will

require hospitals to provide services that meet the clinical criteria established in 907 KAR 3:130.

- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
- (a) Initially: The Department for Medicaid Services (DMS) is unable to determine a precise aggregate fiscal impact of the use of the criteria established in 907 KAR 3:130 to determine clinical appropriateness for multiple programs; however, anticipates a savings of at least \$2.5 million (\$1.7 million federal funds; \$0.8 million state funds) annually.
 - (b) On a continuing basis: DMS is unable to determine a precise aggregate fiscal impact of the use of the criteria established in 907 KAR 3:130 to determine clinical appropriateness for multiple programs; however, anticipates a savings of at least \$2.5 million (\$1.7 million federal funds; \$0.8 million state funds) annually.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement the amendment to this administrative regulation.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used)

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.